

CLAIMS

5 1. A valve prosthesis device suitable for implantation in body ducts, the device comprising:

10 a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length; and

15 a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet,

20 whereby when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

25 2. The valve device of Claim 1, wherein the support stent comprises an annular frame.

3. The valve device of Claim 1, wherein said valve assembly has a tricuspid configuration.

4. The valve device of Claim 1, wherein said valve assembly is made from biocompatible material.

5. The valve device of Claim 4, wherein the valve assembly is made from pericardial tissue, or other biological tissue.

6. The valve device of Claim 1, wherein said valve assembly is made from biocompatible polymers.

7. The valve device of Claim 6, wherein the valve assembly is made from materials selected from polyurethane and polyethylene terphthalane.

8. The valve device of Claim 7, wherein said valve assembly comprises a main body made from polyethylene terphthalane and leaflets made from polyurethane.

5 9. The valve device of Claim 1, wherein said support stent is made from nickel titanium.

10. The valve device of Claim 1, wherein the support beams are substantially equidistant and substantially parallel so as to provide anchorage for the valve assembly.

10 11. The valve device of Claim 1, wherein the support beams are provided with bores so as to allow stitching or tying of the valve assembly to the beams.

12. The valve device of Claim 1, wherein the support beams are chemically adhered to the support stent.

15 13. The valve device of Claim 1, wherein said valve assembly is riveted to the support beams.

14. The valve device of Claim 1, wherein said valve assembly is stitched to the support beams.

15. The valve device of Claim 1, wherein said beams are manufactured by injection using a mold, or by machining.

20 16. The valve device of Claim 1, wherein said valve assembly is rolled over the support stent at the inlet.

17. The valve device of Claim 1, wherein said valve device is manufactured using forging or dipping techniques.

25 18. The valve device of Claim 1, wherein said valve assembly leaflets are longer than needed to exactly close the outlet, thus when they are in the collapsed state substantial portions of the leaflets fall on each other creating better sealing.

19. The valve device of Claim 1, wherein said valve assembly is made from coiled a polymer, coated by a coating layer of same polymer.

20. The valve device of Claim 19, wherein said polymer is polyurethane.

21. The valve device of Claim 1, wherein the support stent is provided with heavy metal markers so as to enable tracking and determining the valve device position and orientation.

22. The valve device of Claim 21, wherein the heavy metal markers are selected from gold, platinum, iridium, or tantalum.

23. The valve device of Claim 1, wherein the valve assembly leaflets are provided with radio-opaque material at the outlet, so as to help tracking the valve device operation *in vivo*.

24. The valve device of Claim 23, wherein said radio-opaque material comprises gold thread.

25. The valve device of Claim 1, wherein the diameter of said support stent, when fully deployed is in the range of from about 19 to about 25 mm.

26. The valve device of Claim 1, wherein the diameter of said support stent may be expanded from about 4 to about 25 mm.

27. The valve device of Claim 1, wherein the support beams are provided with bores and wherein the valve assembly is attached to the support beams by means of u-shaped rigid members that are fastened to the valve assembly and that are provided with extruding portions that fit into matching bores on the support beams.

28. The valve device of Claim 1, wherein the support beams comprise rigid support beams in the form of frame construction, and the valve assembly pliant material is inserted through a gap in the frame and a fastening rod is inserted through a pocket formed between the pliant material and the frame and holds the valve in position.

29. The valve device of Claim 1, wherein the main body of the valve assembly is made from coiled wire coated with coating material.

30. The valve device of Claim 31, wherein the coiled wire and the coating material is made from polyurethane.

5 32. The valve device of Claim 1, wherein a strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion of the valve assembly may flap.

33. The valve device of Claim 32, wherein the strengthening-wire is made from nickel titanium alloy.

10 33. A valve prosthesis device suitable for implantation in body ducts, the device comprising a main conduit body having an inlet and an outlet and pliant leaflets attached at the outlet so that when a flow passes through the conduit from the inlet to the outlet the leaflets are in an open position allowing the flow to exit the outlet, and when the flow is reversed the leaflets collapse so as to block the outlet, wherein the
15 main body is made from polyethylene terphthalate and collapsible leaflets are made from polyurethane.

34. The valve device of Claim 33, wherein support beams made from polyurethane are provided on the main body and wherein the leaflets are attached to the main body at the support beams.

20 35. The valve device of Claim 33, wherein said support beams are chemically adhered to the main body.

36. A valve prosthesis device suitable for implantation in body ducts, the device comprising:

25 support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the

target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length;

valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible
5 slack portions of the conduit at the outlet;

substantially equidistant rigid support beams interlaced or attached to the slack portion of the valve assembly material, arranged longitudinally.

37. A crimping device for crimping the valve device of Claim 1, the crimping device comprising a plurality of adjustable plates that resemble a typical SLR
10 camera variable restrictor, each provided with a blade, that are equally dispersed in a radial symmetry but each plate moves along a line passing off an opening in the center, all plates equidistant from that center opening.

38. The crimping device of Claim 37, wherein the multiple plates are adapted to move simultaneously by means of a lever and transmission.

39. A method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a
15 patient, the method comprising the steps of:

(a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion
20 located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

(b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

(c) providing a deployable implantable valve prosthesis device adapted to
25 be mounted on the second inflatable portion of the balloon catheter

(d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the second inflatable portion of the balloon catheter until the first inflatable portion of the balloon catheter is inserted into the left

ventricle, whereas the second inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

(e) inflating the first inflatable portion of the balloon catheter so as to substantially block blood flow through the natural aortic valve and anchor the distal end of the balloon catheter in position;

(f) inflating the second inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

(g) deflating the first and second inflatable portions of the balloon catheter; and

(h) retracting the balloon catheter and removing it from the patient's body.

40. The method of Claim 39, wherein the guiding tool comprises a guide wire.

41. A method for deploying an implantable prosthesis valve device at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient, the method comprising the steps of:

(a) providing a balloon catheter having a proximal end and a distal end, having a first and second independently inflatable portions, the first inflatable portion located at the distal end of the catheter and the second inflatable portion adjacently behind the first inflatable portion;

(b) providing a guiding tool for guiding the balloon catheter in the vasculature of the patient;

(c) providing a deployable implantable valve prosthesis device adapted to be mounted on the first inflatable portion of the balloon catheter, and a deployable annular stent device adapted to be mounted over the second inflatable portion of the balloon catheter, the deployable implantable valve prosthesis device and the deployable annular stent kept at a predetermined distant apart;

(d) guiding the balloon catheter through the patient's aorta using the guiding tool, the valve device mounted over the first inflatable portion of the balloon catheter and the deployable annular stent mounted over the second inflatable portion of the balloon catheter, until the first inflatable portion of the balloon catheter is positioned at the natural aortic valve position;

(e) inflating the second inflatable portion of the balloon catheter so that the deployable stent device is deployed within the aorta thus anchoring the deployable annular stent and the coupled valve device in position;

(f) inflating the first inflatable portion of the balloon catheter so as to deploy the implantable prosthesis valve device in position at the natural aortic valve position;

(g) deflating the first and second inflatable portions of the balloon catheter; and

(h) retracting the balloon catheter and removing it from the patient's body.